

**REMARKS/ARGUMENTS**

By this Amendment, claims 1, 3-4, 6-9, 11, 14-15, 17, 19 and 23-26 are amended and claim 22 is canceled. Claims 1-21 and 23-26 are pending.

Favorable consideration is respectfully requested in view of the foregoing amendments and the following remarks.

**Claims Rejections – 35 U.S.C. § 112**

Claims 1-26 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. This rejection is respectfully traversed.

Applicants respectfully submit that the Examiner has failed to apply the appropriate standard for evaluating the definiteness of claims, as set forth in MPEP § 2173.02:

The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. . . . The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

a) Claim 1 – “biological material”

According to the Office Action, the expression “‘biological material’ is uncertain as to meaning and scope. Material that is biological and not biological is relative and subjective and would be uncertain.”

A person having ordinary skill in the art (a PHOSITA) would understand the expression “biological material” based on the combined conventional meanings of the component terms of the expression. The expression generates over 500,000 hits in a Google search (Exhibit A), including the definition of the expression in a Wikipedia entry (Exhibit B) and the use of the term in the MPEP at Section 2404.01, which is entitled “Biological Material That Is Known and Readily Available to the Public - 2400 Biotechnology”.

Moreover, over 900 U.S. patents since 1976 contain the expression “biological material” in the claims (Exhibit C), including 25 patents issued by Examiner Naff (Exhibit D).

If the expression “biological material” is clear enough for use in the patent regulations and clear enough for use in over 900 U.S. patents issued since 1976, it is clear enough to use in the present claims. As noted in MPEP 2173.02:

[I]f the language used by applicant satisfies the statutory requirements of 35 U.S.C. 112, second paragraph, but the examiner merely wants the applicant to improve the clarity or precision of the language used, the claim must not be rejected under 35 U.S.C. 112, second paragraph, rather, the examiner should suggest improved language to the applicant. . . . If applicant does not accept the examiner's suggestion, the examiner should not pursue the issue.

b) Claim 1 – “nanoparticulate reinforcing material”

The Office Action at page 2, lines 20-25 states:

“[N]anoparticulate reinforcing material” is unclear how “reinforcing” defines the material since the material that is reinforced and the result that is being reinforced is not specified. The difference in nanoparticulate material that is reinforcing and not reinforcing would be relative and subjective and uncertain.

The meaning of the expression is clear in view of the teachings of the specification. A PHOSITA would have understood from, e.g., the following passage from the specification at page 4, lines 13-21:

A nanoparticulate, gel-forming and cross-linking reinforcing material is used. The homogenous embedding of the biomaterial into the composite material results in a high degree of immobilization, and therefore a high stability and long lasting effectiveness of the composite material. The reinforcing material contained within the composite material enables the use of a procedure for the reinforcement of ceramic at low temperatures, which is gentle for the biomaterial.

that the expression “nanoparticulate reinforcing material” as used in the context of the claims means a material comprising nanoparticles, which material reinforces the ceramic substrate of the ceramic composite.

c) Claim 1 – “nanoparticles that are linked to one another”

The Office Action at pages 2-3 states:

Bridging the last two lines, claim 1 is unclear what links the nanoparticles together, and when the nanoparticles are linked, i.e., before being embedded in the ceramic substrate or after being embedded. In the last line, claim 1 is unclear as to when the nanoparticles are formed from a nanoparticulate sol, i.e. before or after the nanoparticles are embedded in the substrate, and it is uncertain as to steps involved in forming the nanoparticles from the sol. When process limitations are required, clear, distinct and positive process steps should be set

forth. The claim is unclear as to what crosslinks the substrate material in the last line. The claim is unclear as to the functional relationship of the nanoparticles being linked to being formed from the sol and to the cross-links of the substrate.

The linking of the nanoparticles with each other and with the substrate material occurs via a gelling step as outlined in detail on e.g., page 7 of the specification and recited in amended process claim 15. Unlike claim 15, however, claim 1 is not a process claim. Claim 1 is a composition claim. There is no basis for requiring Applicants to specify process limitations in a composition claim.

d) Claim 3 – “hydrolysis products of trialkoxy silanes, or mixtures thereof”

The meaning of “products of trialkoxy silanes” is clear in view of the teachings of the specification at page 5, lines 29-35.

The expression “mixtures thereof” is deleted from claim 3 to obviate any basis for the rejection relating thereto.

e) Claims 4, 9 and 14 – “a proportion of”

The expression “a proportion of” is deleted from claims 4, 9 and 14 to obviate any basis for the rejection relating thereto.

f) Claim 6 – “cell groups” and “biologically effective macromolecules”

According to the Office Action at page 3, lines 22-24, in claim 6, “cell groups” and “biologically effective macromolecules” are uncertain as to meaning and scope and materials that are within and not within the scope of these terms.

Claim 6 is amended to obviate any basis for the rejection as it pertains thereto. In particular, the expression “cell groups” now reads “cell aggregates” and “biologically effective macromolecules” is substituted with the expression “bioactive molecular agents”. Support for the amendments is apparent in the specification at, e.g., page 6, lines 14-15 and 20-22, which passages of the specification also clarify the meaning of the amended claim.

g) Claim 7 – “living” vs. “viable”

In claim 7, the term “viable” is intended to include such items as spores of a bacterium or yeast, which may be regarded by those skilled in the art as not yet living but possessing the potential for life under certain conditions. This definition is in accordance with the conventional meaning of the term, as evidenced by Exhibit E, a definition of the term “viable” from Merriam-Webster’s Online Medical Dictionary.

h) Claim 9 – “groups”

The term “aggregates” is substituted for the term “groups” to clarify that the claim limitations at issue are meant to define a plurality of cells rather than refer to some unspecified classification system for cells.

i) Claims 9 and 14 – “a” vs. “the”

The article “a” is appropriately used to first introduce a limitation that has not previously been recited in the claim or any claims from which the claim ultimately depends. Since the limitation “dry weight of the composite material” in claims 9 and 14 is not previously introduced in those claims or any claims from which they ultimately depend, the article “a” is appropriate and is not substituted with the article “the” as suggested in the Office Action at page 4.

j) Claim 11 – “additive that increases biological activity”

The Office Action at page 4, lines 12-14, alleges that “Claim 11 is unclear as to an additive that increases biological activity since a material that has biological activity has not been previously required.”

Claim 11 is amended to obviate any basis for this rejection. It now clarifies that the biological activity referenced in the claim is that of the at least one biological material of base claim 1. Biological materials inherently possess biological activity (or the potential for biological activity) by definition.

k) Claim 15 – alleged failure to set forth clear, distinct and positive steps

Claim 15 is amended to obviate any basis for this rejection. Claim 15 now specifies additional features with respect to the gelling and cross-linking step as outlined in detail on page 7 of the specification.

The issue relating to the term “neutralization” in claim 15 (and in claim 26, discussed below) appears to be based on a misunderstanding. The nanoparticulate material is not the means by which neutralization occurs. The Examiner is correct that neutralization is indeed effected, as usual, by adding an appropriate pH adjusting agent. Therefore, the relevant passage of claim 15 is amended as follows: “neutralization of the slurry ~~with~~containing the at least one nanoparticulate reinforcing material”.

The “freezing process” of claim 15 (not claim 14 as erroneously identified in the Office Action at page 5, lines 3-6) is now identified as a “freeze-casting process”, which is described in the specification at pages 7 and 10-11.

l) Claim 14 – timing of nanoparticulate formation

Claim 14, like claim 1, is a composition claim. There is no basis for requiring Applicants to specify process limitations in a composition claim.

m) Claim 17 – “additional additives”

Claim 17 is amended to obviate any basis for this rejection. The additives are no longer referred to as being “additional”.

n) Claim 21 – biocatalyst and biofilter vs. ceramic composite material

According to the Office Action at page 5, lines 13-16:

Claim 21 in line 4 is unclear as to how the biocatalyst and biofilter differ from the ceramic composite material since structure 15 of the biocatalyst and biofilter has not been required that is different from the ceramic composite material structure.

This basis for the rejection improperly assumes that the biocatalyst and biofilter necessarily differ from the ceramic composite material. The biocatalyst in its most elemental form can simply be the ceramic composite material according to claim 1, used for biocatalysis. The biofilter in its most elemental form can simply be the ceramic composite material according to claim 1, used for filtration.

o) Claim 22

Claim 22 is canceled to obviate any basis for the rejection relating thereto.

p) Claims 23-24 – “molding”

The ambiguous term "molding" in claims 23 and 24 has been replaced by the expression “molded article”, which is more consistent with the original German term “Formkörper” in the international application.

q) Claim 25 – “freezing process”

Claim 25 is amended to obviate any basis for this rejection. The freezing (now freeze-casting) step is now defined in more detail.

r) Claim 26 – “neutralization”

Claim 26 is amended to obviate any basis for this rejection.

Accordingly, reconsideration and withdrawal of the indefiniteness rejection is respectfully requested.

### **Claims Rejections – 35 U.S.C. § 103**

Claims 1-26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kuehn et al. (DE 10065138) in view of Trieu et al. (US 20020115742) and Bottcher et al. (DE 19929616) and Wei et al. (US 6696258). This rejection is respectfully traversed.

Kuehn et al., already mentioned in the present application, is an earlier patent of the present inventor Dr. Martina Kuehn (or Kühn), but differs in several important aspects from the invention as presently claimed. Perhaps the statements on the bottom of pages 2 and 4 of the application referring to the present invention as a modification of the method of DE 10065138 were somewhat misleading. It is correct that both methods relate to the low-temperature preparation of a ceramic material and that the ceramic composite material of the present invention comprises a nanoparticulate reinforcing material and a biomaterial in addition to the ceramic substrate material.

The prior art process according to claim 1 of the cited reference comprises:

- a) preparing of a sol from a mixture of aluminium hydroxide or  $\text{AlOOH}$ , aluminium oxide fibers and an aqueous solution of sodium aluminate with an excess of the base ( $\text{NaOH}$ );
- b) converting of the sol into the gel phase (which gelling is induced by the excess of conc.  $\text{NaOH}$ );
- c) freezing of the gel to produce ice crystals from the solvent;
- d) removal of the solvent by thawing and drying to provide funnel-like pores;
- e) removal of the sodium ions by lixiviation with mineral acid; and
- f) optionally sintering the material.

In this process, the slurry is highly basic (which is necessary to induce the gelling of the components) and no biological cells would survive therein. The freezing step is conducted after the gelling to provide pores of a defined funnel-like structure, whereas in the first embodiment of the process of present invention the gelling is induced by the freezing.

Further, the dried material obtained after step d) of the reference process is mechanically unstable and has to be treated with mineral acid. This step as well would not be possible in the presence of living organisms.

In the process of the present invention, neither the ceramic substrate material nor the reinforcing material as the inorganic components of the slurry are highly basic and the gel-forming material is different from the ceramic substrate material. As outlined in detail on page 7 of the specification, the resulting gel phase envelops the grains of the ceramic material and, thus, embeds or cross-links said grains. Direct covalent bonds exist between the nanoparticles of the gel but are usually not present between the gel particles and the ceramic grains (or the biomaterial) or only in a minor proportion and are not required for the linking.

If the reinforcing material is a silicon-based sol or gel, respectively, which is a preferred embodiment, the gel is formed by Si-O-Si bonds between the nanoparticles and a 3-dimensional net-like matrix results. No lixiviation with mineral acid is required.

A further major advantage of the present method resides in the fact that the biomaterial may be added during the mixing of the components of the ceramic composite material which results in a homogenous distribution of the biomaterial and allows the incorporation of a relatively large amount thereof.

Thus, the composition of the present invention cannot be obtained, and the process of the present invention cannot be implemented by conducting a process according to DE10065138 and simply further adding a nanoparticulate reinforcing material and a biomaterial.

With respect to the remaining documents cited, each of said documents relates to methods and compositions quite different from claimed subject matter.

In particular, Wei et al. describes a process for preparing a mesoporous material wherein a pore-forming material such as glucose or a polyol or polyacid is used as a kind of spacer during the formation of an inorganic, specifically a silicon-based, matrix and wherein at least the major part of said pore-forming material subsequently has to be removed, e.g. by calcination or solvent extraction, to provide the desired pores.

A ceramic material is only obtained by a high-temperature sintering process such as calcination. In this case, however, a biomaterial such as living organism or proteins, in particular enzymes, could only be added after the sintering. In the major part of the examples described, conventional non-ceramic hydrogels or xerogels are produced.

Trieu et al. disclose orthopedic compositions comprising a homogenous mixture of a biocompatible organic polymer and a bioactive particulate ceramic (such as hydroxyapatite;

HAP), wherein the ceramic particles are imbedded in the organic polymer matrix. No sol-gel-technique is use for preparing an inorganic matrix. Bioactive in this context means capable to be degraded and resorbed by the cells of the body to provide a source material for bones.

Boettcher at al. teaches the use of a sol-gel-technique to prepare a phosphorous-silicate-based nanosol coating composition, which may be sintered at a temperature of at least 400°C to obtain a ceramic coating capable to protect a substrate from thermal oxidation. This method only provides very thin layers of a few  $\mu\text{m}$ , the preparation of 3-dimensional molded or shaped articles as obtainable by the method of the present invention is not possible with the method of this prior art.

Additionally, once more the high-temperature sintering step prevents the inclusion of biomaterial.

Evidently, a PHOSITA would not have been motivated to combine the specific teachings of any one of Wei et al., Trieu et al., or Boettcher et al. with one another or with the disclosure of Kuehn et al., to reach the claimed invention with a reasonable expectation of success. As noted in the specification at page 5, lines 2-4:

It was surprisingly shown that the method according to the invention enables the reinforcement of the composite at room temperature, or at lower temperatures.

This unexpected result enables the claimed method to provide the claimed composite material containing at least one biological material without destroying the biological material in the process.

Moreover, the proposed combination of reference teachings fails to meet all the limitations of the claimed invention due to the differences between the present method and the method of DE10065138 as outlined above.

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.



App. Serial No. 10/540,936  
Amendment Dated 7/11/2008  
Response to Office Action of 4/11/2008

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOW, LTD.

July 11, 2008

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The Uniform **Biological Material** Transfer Agreement. March 8, 1995. I. Definitions:. 1.

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**Uniform Biological Material Transfer Agreement**

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Human **Biological Material** means any material that comes from a person (e.g., ... Human

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**95-02: PHS Uniform **Biological Material** Transfer Agreement**

The Uniform **Biological Material** Transfer Agreement (UBMTA) (Exhibit A-I) and related documents were published in the Federal Register on March 8, ...  
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EX. B

# Biological material

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From Wikipedia, the free encyclopedia

**Biological material** may refer to:

- Biological tissue, or just *tissue*
- Biomass, living or dead biological matter, often plants grown as fuel
- Biomass (ecology), the total mass of living biological matter
- Biomaterials
- Biocompatible materials and bioapplicable materials
- Biomolecule, a chemical compound that naturally occurs in living organisms
- Biotic material, from living things
- Bio-based material, a processed biotic material
- Cellular component, material and substances of which cells (and thus living organisms) are composed
- Organic material (or organic matter), derived from living things or containing carbon
- Viable material, capable of living, developing, or germinating under favorable conditions. (*see: viability*)
- Body fluids

Retrieved from "[http://en.wikipedia.org/wiki/Biological\\_material](http://en.wikipedia.org/wiki/Biological_material)"

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EX. C

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aclm/"biological material"

- | PAT.<br>NO.  | Title  |
|--------------|--|
| 1 7,395,693  | <a href="#">T Embedded piezoelectric microcantilever sensors</a>   |
| 2 7,391,515  | <a href="#">T Automated visual inspection system for the detection of microbial growth in solutions</a>                                      |
| 3 7,385,697  | <a href="#">T Sample analysis methodology utilizing electromagnetic radiation</a>  |
| 4 7,384,403  | <a href="#">T Wireless communication system for transmitting information from a medical device</a>   |
| 5 7,381,559  | <a href="#">T Fermentation flask for cultivating microorganisms</a>  |
| 6 7,381,440  | <a href="#">T Biological laser printing for tissue microdissection via indirect photon-biomaterial interactions</a>                          |
| 7 7,377,938  | <a href="#">T Prosthetic cardiac valve and method for making same</a>  |
| 8 7,377,400  | <a href="#">T Stacked assembly of disposable biohazard containment bags having a reinforced holder</a>                                       |
| 9 7,374,573  | <a href="#">T System and method for improving ventricular function</a>   |
| 10 7,371,830 | <a href="#">T Method for separating biological material from a fluid using magnetic particles</a>  |
| 11 7,371,742 | <a href="#">T Porphyrin derivatives for photodynamic therapy</a>   |
| 12 7,368,710 | <a href="#">T Sample preparation method</a>  |
| 13 7,368,570 | <a href="#">T Organometallic complexes as singlet oxygen sensitizers</a>   |
| 14 7,368,234 | <a href="#">T Physical mapping method using molecular combing technique allowing positioning of a great number of clones within a genome</a> |
| 15 7,364,853 | <a href="#">T Detection of microsatellite instability and its use in diagnosis of tumors</a>   |
| 16 7,364,564 | <a href="#">T Implant having MEMS flow module with movable, flow-controlling baffle</a>  |
| 17 7,354,764 | <a href="#">T Method and device for culturing cells</a>  |
| 18 7,354,749 | <a href="#">T Decellularisation of matrices</a>  |
| 19 7,351,575 | <a href="#">T Methods for processing biological materials using peelable and resealable devices</a>  |



Ex. D

# USPTO PATENT FULL-TEXT AND IMAGE DATABASE

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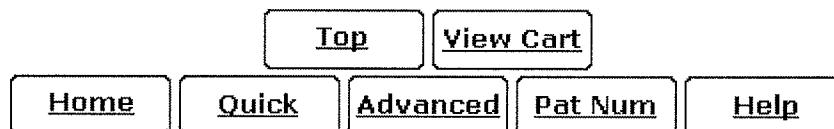
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PAT. NO.	Title
1 7,371,830	<a href="#">T Method for separating biological material from a fluid using magnetic particles</a>
2 7,160,716	<a href="#">T Device for inducing an immune response in cancer therapy</a>
3 6,649,384	<a href="#">T System and method for encapsulating biological material by applying electrostatic charge to capsules</a>
4 6,596,274	<a href="#">T Biological material containing bone marrow stem cells partially or completely differentiated into connective tissue cells and a hyaluronic acid ester matrix</a>
5 6,403,376	<a href="#">T Ultra rapid freezing for cell cryopreservation</a>
6 6,395,467	<a href="#">T Cryoprotectant solution containing dimethyl sulfoxide, an amide and ethylene glycol</a>
7 6,300,130	<a href="#">T Ultra rapid freezing for cell cryopreservation</a>
8 6,255,477	<a href="#">T Particles having a magnetic core and outer glass layer for separating biological material</a>
9 5,807,757	<a href="#">T Preparation of ionically cross-linked polyphosphazene microspheres by coacervation</a>
10 5,663,306	<a href="#">T Method of conjugating an activated ester to an amine-containing biological material</a>
11 5,643,773	<a href="#">T Preparation of elongated seamless capsules containing a coaxial rod and biological material</a>
12 5,521,079	<a href="#">T Microcapsule generating system containing an air knife and method of encapsulating</a>
13 5,462,866	<a href="#">T Semipermeable microspheres encapsulating biological material</a>
14 5,418,154	<a href="#">T Method of preparing elongated seamless capsules containing biological material</a>
15 5,387,522	<a href="#">T Apparatus having a biphasic spray head for entrapping biological material in a hydrophilic gel</a>
16 5,116,747	<a href="#">T Immobilization of biologically active material in capsules prepared from a water-soluble polymer and chitosan acetate</a>
17 5,089,407	<a href="#">T Encapsulation of biological material in non-ionic polymer beads</a>
18 RE33,441	<a href="#">T Immobilization of biologically active material with glutaraldehyde and polyazetidine</a>
	<a href="#">T</a>

- 19 [4,933,284](#) [Regenerable dialkylaminoalkyl cellulose support matrix for immobilizing biologically active materials](#)
- 20 [4,914,021](#) **T** [Carcinoma orosomucoid-related antigen, a monoclonal antibody thereto, and their uses](#)
- 21 [4,892,825](#) **T** [Immobilization of biologically active material with glutaraldehyde and polyazetidine](#)
- 22 [4,774,178](#) **T** [Immobilization of biological material within a polymer matrix](#)
- 23 [4,582,805](#) **T** [Immobilization of biological matter via copolymers of isocyanatoalkyl esters](#)
- 24 [4,434,228](#) **T** [Immobilization of biological materials in condensed polyalkyleneimine polymers](#)
- 25 [4,237,229](#) **T** [Immobilization of biological material with polyurethane polymers](#)
- 





EX. E

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## Medical Dictionary

One entry found for **viable**.

Main Entry: **vi·a·ble**

Pronunciation: **ˈvī-ə-bəl**

Function: *adjective*

**1** : capable of living <the skin graft was *viable*> <*viable* cancer cells>; *especially* : having attained such form and development as to be normally capable of living outside the uterus -- often used of a human fetus at seven months but may be interpreted according to the state of the art of medicine <a *viable* fetus is one sufficiently developed for extrauterine survival -- *Words & Phrases*> <the fetus is considered *viable* when it weighs 500 grams or more and the pregnancy is over 20 weeks in duration -- S. W. Jacob & C. A. Francone>  
**2** : capable of growing or developing <*viable* eggs>

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## Pronunciation Key

\ ə \ as a in abut	\ g \ as g in go	\ r \ as r in red
\ ɪ ə \ as u in abut	\ h \ as h in hat	\ s \ as s in less>
\ e \ as e in kitten	\ i \ as i in hit	\ sh \ as sh in shy
\ ər \ as ur/er in further	\ ī \ as i in ice	\ t \ as t in tie
\ a \ as a in ash	\ j \ as j in job	\ th \ as th in thin
\ ā \ as a in ace	\ k \ as k in kin	\ th \ as th in the
\ ä \ as o in mop	\ ḳ \ as ch in ich dien	\ ū \ as oo in loot
\ aũ \ as ou in out	\ l \ as l in lily	\ ũ \ as oo in foot
\ b \ as in baby	\ m \ as m in murmur	\ v \ as v in vivid
\ ch \ as ch in chin	\ n \ as n in own	\ w \ as w in away
\ d \ as d in did	\ ŋ \ as ng in sing	\ y \ as y in yet
\ e \ as e in bet	\ ō \ as o in go	\ yũ \ as you in youth
\ ɛ ē \ as ea in easy	\ ô \ as aw in law	\ yü \ as u in curable
\ ē \ as y in easy	\ ói \ as oy in boy	\ z \ as z in zone
\ f \ as f in fifty	\ p \ as p in pepper	\ zh \ as si in vision

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